

Terms of Reference and Rules of Procedure
Task Force on Method of Supply of
antiparasitic veterinary medicinal products
that are indicated for food-producing
animals

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1 ESTABLISHMENT

- 1.1 The Task Force on Method of Supply of antiparasitic veterinary medicinal products that are indicated for food-producing animals is established by the Authority of the HPRA, following the advice of the Advisory Committee for Veterinary Medicines (ACVM).

2 MANDATE

- 2.1 To review the current methods of supply of antiparasitic veterinary medicinal products that are authorised by the HPRA for food-producing animals as not requiring prescription control and to produce a report on assess their legal supply route against the criteria established by Regulation (EU) 2019/6/EU. For the purposes of this review, antiparasitic veterinary medicinal products includes anthelmintics, ectoparasitic products and veterinary medicinal products containing coccidostats.
- 2.2 The report should provide advice to the ACVM, and consider:
- The current situation,
 - The scientific evidence available,
 - The criteria set out in Article 34 of Regulation (EU) 2019/6,
 - The practical experience in the supply of antiparasitic veterinary medicinal products for food-producing animals that do not require a prescription in Ireland currently,
 - If relevant, the position on such products in other EU Member States,
 - Developing trends in agriculture, veterinary medicines or animal diseases and how these might be influenced by the current and future supply methods,
 - The likely risks, if any, associated with maintaining the current regulatory regimen,
 - The likely impact of any change of method of supply, in terms of ensuring the quality, safety and efficacy of use of the medicine, as well as its impact on animal health and welfare, and on stakeholders,
 - If a change to the existing method of supply is considered warranted, to outline how best that change should be made (timeframe, logistics etc.),
 - To consider any other relevant facts it deems appropriate to compile this report.
- 2.3 The task force will be expected to consult with interested parties, as necessary, before finalising the report.

3 COMPOSITION

- 3.1 The task force consists of seven members, appointed by the HPRA following the agreement of the Chairperson of the ACVM.
- 3.2 Members are appointed for the period until the report is completed.
- 3.3 Members of the task force are paid allowances for expenses as the Authority may, with the consent of the Ministers and the Minister for Finance, determine.

4 CHAIRPERSON

- 4.1 The Chairperson is appointed by the task force from among the members of the task force.

- 4.2 The Chairperson is responsible for the efficient conduct of the business of the task force, in particular by:
- planning the work of the task force together with the task force,
 - monitoring that the rules of procedure are respected,
 - ensuring that at the beginning of each meeting, any potential conflict of interest is declared regarding any particular item to be discussed by the task force,
 - aiming to achieve consensus on issues discussed by the task force,
 - ensuring, together with the task force, the regulatory and scientific consistency of the task force's recommendations,
 - co-ordinating the work of the task force, and
 - reporting on the activities of the task force as appropriate.

5 MEETINGS

- 5.1 Meetings are held with sufficient frequency to enable the task force to carry out its functions. Normally, meetings are held every six weeks to two months. If appropriate, the Chairperson will consult with the staff of the Authority in determining the frequency of meetings.
- 5.2 Members of the task force may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting. An administrative official of the Authority may also attend the meetings to assist the conduct of the meeting, but are not entitled to participate.
- 5.3 Meetings are chaired by the Chairperson. In his/her absence, an acting Chairperson is appointed from among the members of the task force.
- 5.4 The task force may act in the absence of one or more members. If members cannot attend all or part of a meeting, they should notify the administrative official to the task force in advance of the meeting.
- 5.5 The quorum for meetings is one half of the appointed task force membership plus one.
- 5.6 The agenda is established by the Chairperson and if appropriate, in consultation with the task force or members of the staff of the Authority. The agenda is circulated with related papers in advance of the meeting.
- 5.7 Each member of the task force present has one vote. Decisions are made by consensus or by a majority of the votes of the members present. If there is an equal division of votes, the Chairperson has a casting vote.
- 5.8 Any employee of the Authority or other person may be invited to attend for particular items at the discretion of the Chairperson but they are not entitled to vote.

6 RECORD OF MEETINGS

- 6.1 Records of each meeting are prepared by the member from the Authority, with the assistance of an administrative official from the Authority.
- 6.2 The records indicate the names of the attendees, and in respect of each item on the agenda:
- the documents submitted to the task force,

- a summary record of the proceedings,
- the decisions taken or the conclusions reached by the task force.

6.3 Draft records are sent to members before the next meeting. They are adopted at the following meeting.

7 REPORTING

7.1 The report, when completed, is provided to the ACVM and then to the Authority.

7.2 The report is to be completed before 4 October 2019.

7.3 The report is expected to be published on the HPRA website, once it has been considered by the ACVM and the Authority.

8 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

8.1 The names of the task force members and their professional qualifications are made public.

8.2 Members of the task force will make a declaration of financial or other beneficiary interest in any industry regulated by the Authority.

8.3 At each meeting, members will declare any financial or other beneficiary interest in any agenda item. When a member is unable to participate in a meeting due to a conflict of interest, he or she must inform the Chairperson of the task force in advance of the meeting in writing. He or she will withdraw from the meeting while the item is considered and will not vote or act as a member in relation to it.

8.4 Members of the task force will abide by the Code of Conduct approved by the Authority.

8.5 Members of the task force are required not to disclose information received by them while performing their duties, even after their duties have ceased.

9 GENERAL PROVISIONS

9.1 These terms of reference and rules of procedure are approved by the Authority and the task force, and are made public.

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